[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request:

Interactive Informed consent for Pediatric Clinical trials

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute Heart, Lung, and Blood Institute (NHBLI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Victoria Pemberton, Clinical Trials Specialist, National Heart, Lung, and Blood Institute NIH, 6701 Rockledge Drive, Room 8102, MSC 7940, Bethesda, MD, or call non-toll-free number 301-435-0510, or E-mail your request, including your address to: pembertonv@nhlbi.nih.gov . Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Interactive Informed Consent for Pediatric Clinical Trials, 0925-New, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will compare parents' and children's understanding of information about a hypothetical clinical trial presented using either a standard paper consent document or an interactive computer-based consent

program. Parents' and children's understanding, regardless of whether they received the standard consent or the interactive computer-based program, will be assessed by face-to-face interview. In addition, parents' and children's perceptions of, and satisfaction with, the information presented will be evaluated by completion of a short questionnaire. The primary hypothesis to be tested is that interactive computer-based research consent information is better understood and accepted by parents and children compared with the standard paper consent document. Given that many individuals have difficulty reading and interpreting standard written consent documents, this technology holds promise as a means to optimize the consent and assent process particularly among individuals with low literacy and numeracy skills.

OMB approval is requested for 18 months. There are no costs to respondents other than their time. The total estimated annualized burden hours are 201.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Response	Average Burden per Response (in hour)	Total Annual Burden Hours
Parents	148	1	40/60	99
Children	136	1	45/60	102

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Lynn Susulske

NHLBI Project Clearance Liaison

National Institutes of Health

Michael S. Lauer

Director, DCVS

National Institutes of Health

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